

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALLERGAN, INC., et al.	:	CIVIL ACTION
	:	
v.	:	NO. 23-272
	:	
MANKIND PHARMA LTD.	:	

ORDER

AND NOW, this 22nd day of July 2024, upon review of defendant Mankind’s motion to vacate the September 27, 2023 stipulation and order precluding Mankind from challenging the validity of the 504 patent and to amend the answer to add the affirmative defense of invalidity based on obviousness-type double patenting (DI 92, 93, 94), Plaintiffs’ Allergan and AbbVie’s response (DI 99), and Mankind’s reply (DI 108), it is **ORDERED** that the motion to vacate and to amend (DI 92) is **DENIED** for the reasons outlined below:

1. On September 26, 2023, the parties in this case freely agreed to and jointly filed a stipulation and proposed order, which Judge Andrews granted the following day. DI 59; DI 60. In that stipulation, defendant Mankind agreed it would “not contest the validity and/or enforceability of any claim of [U.S. Patent No. 7,851,504] in this action.” DI 60 at 2.

2. Mankind now seeks to vacate the stipulation and argue that the 504 patent is invalid due to obviousness-type double patenting over the later-filed, later-issued, but earlier-expiring, U.S. Patent No. 8,338,479.

3. “[I]t is a well-recognized rule of law that valid stipulations entered into freely and fairly, and approved by the court, should not be lightly set aside.” *Waldorf v. Shuta*, 142 F.3d 601, 616 (3d Cir. 1998). However, stipulations are not absolute, and a party may withdraw from a stipulation if the court finds the moving party has demonstrated “exceptional circumstances” and that “there will be manifest injustice unless [the moving] party is relieved from [the]

stipulation.” *Id.* at 617. A court considers four factors to determine whether enforcement of the stipulation will create a manifest injustice: “(1) the effect of the stipulation on the party seeking to withdraw the stipulation, (2) the effect on the other parties to the litigation, (3) the occurrence of intervening events since the parties agreed to the stipulation, and (4) whether evidence contrary to the stipulation is substantial.” *Waldorf*, 142 F.3d at 617–18 (citations omitted). This approach is more apt for factual or evidentiary stipulations (and motions to vacate typically arise from those sort of stipulations), but the parties do not seem to disagree that it is the applicable framework. Here we will focus on the first three factors as a guide to determine if “exceptional circumstances” now require us to vacate the stipulation to avoid “manifest injustice.”

4. Starting with the prospect of prejudice to the parties, Mankind argues that it will suffer manifest injustice because its competitors will be able to rely upon an expected Federal Circuit decision¹ to invalidate the ’504 patent, while the stipulation will bar Mankind from making the same arguments. DI 93 at 13. Mankind argues that vacating the stipulation will not be unfair to Allergan because Allergan is defending against the same invalidity arguments in another ongoing litigation,² and has already responded to a Rule 12(c) motion asserting that same invalidity argument. Mankind also argues that its double-patenting defense would not require any additional fact discovery because it is “anticipation-type” in nature. *Id.* at 15; DI 108 at 8–9.

5. Plaintiffs argue that upholding the stipulation is not prejudicial to Mankind

¹ The case is an appeal from *Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, 694 F. Supp. 3d 511 (D. Del. 2023) (“*MSN*”), which issued the day after the stipulation was entered in this case.

² *Allergan, Inc. v. Amneal Pharms. of N.Y., LLC*, No. 2:23-cv-06208-NJC-ST (E.D.N.Y. filed Aug. 17, 2023).

because the parties freely agreed to it in light of strategic considerations. DI 99 at 12. Plaintiffs contend that vacating the stipulation will prejudice plaintiffs by causing “significant additional work, including follow-on discovery requests,” because they are not required to offer the same response to the double-patenting defense in this case as they have in the ongoing E.D.N.Y. case, and are free to seek additional information and develop different responses. *Id.* at 12–13.

Plaintiffs contend that if we were to vacate the stipulation, they would be harmed because the deadline for completing fact discovery has passed (as of the date of this order). *Id.* at 13–14.

Plaintiffs also point out that the deadline for invalidity contentions was August 11, 2023, and vacating the stipulation would essentially allow Mankind to circumvent the scheduling order. *Id.*

6. Regarding the occurrence of intervening events, Mankind argues that if the Federal Circuit affirms the *MSN* decision, there will be a change in the law that will render the 504 patent invalid for double patenting. DI 108 at 1–2, 7. Mankind admits that the Federal Circuit’s decision is still pending but argues that now is the proper time to bring its motion to avoid prejudice to Allergan. DI 93 at 17–18; DI 108 at 6.

7. Allergan does not concede that the double-patenting defense will automatically succeed, and counters that if the Federal Circuit affirms the *MSN* decision, the law will not change. DI 99 at 10. Rather, it would be an affirmation of what Judge Andrews characterized as following the existing law, including *In re Collect*, 81 F.4th 1216 (Fed. Cir. 2023).³ *Id.* And, if the Federal Circuit reverses the *MSN* decision, that change in the law would defeat Mankind’s would-be argument. *Id.*

³ *In re Collect* was decided on August 28, 2023, about a month before the stipulation was entered in this case. *In re Collect*, 81 F.4th at 1216.

8. Even assuming that the *MSN* decision is affirmed by the Federal Circuit,⁴ we find that there are no exceptional circumstances leading to manifest injustice to Mankind that justify vacating the stipulation. Furthermore, vacating the stipulation at this point in the case would be prejudicial to plaintiffs.

9. At oral argument, Mankind and plaintiffs agreed that the decision to create the stipulation was purely strategic. The parties were disputing the scope and extent of discovery (into information relating to objective indicia of nonobviousness). DI 124 at 6:14–9:2. Mankind voluntarily decided to sign the stipulation because it would streamline the case and would allow them to avoid answering discovery requests. *See id.* Mankind argues that part of its rationale for agreeing to the stipulation was that the 504 patent had been unsuccessfully challenged in the past and the invalidity theories that remained were weak. *See id.* at 6:23–7:12; DI 93 at 5.

10. Even if *MSN* turns out just the way Mankind hopes, that is not an exceptional circumstance. Mankind agreed to “not contest the validity and/or enforceability of any claim of ’504 patent in this action.” DI 60 at 2. When Mankind signed the stipulation and asked the court to enter an order, it was aware that invalidity theories existed that it could have used in defense of Plaintiffs’ claims of infringement. Mankind may have believed those arguments would not

⁴ Mankind repeatedly argued in briefing that based on the Federal Circuit’s oral argument in *MSN*, the decision would likely be an affirmance and give Mankind the precedent it hopes for. Maybe, maybe not. We found Judge Williams’s analysis disagreeing with Judge Andrews on the same issue persuasive. *See Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, No. CV 20-985-GBW, 2023 WL 8803448, at *7 (D. Del. Dec. 13, 2023). It is entirely unclear why a later-filed, later-issued, earlier-expiring patent should serve as an OTDP reference to invalidate an earlier-filed, earlier-issued, later-expiring patent. What purpose of the judicially created doctrine of obviousness-type double patenting — especially post-URAA — would that serve? In any event, that issue is not briefed here, and we can dispose of this motion on the assumption that *MSN* is affirmed.

have been successful, but it was a tactical decision not to assert them. And even if the *MSN* decision is affirmed, and the decision ought to be viewed as “new law” so to speak, new theories of invalidity do not alter the position that Mankind was in when it signed the stipulation.

Mankind is represented by sophisticated counsel who are well aware, now and at the time the stipulation was entered, that the law controlling invalidity is subject to change. The history of obviousness-type double patenting is a graveyard of patents invalidated by surprising (to me, anyway) judicial decisions. Mankind knowingly gave up all its invalidity defenses — weak ones and strong ones, known ones and unknown ones.

11. This motion puts the parties in an awkward position. Mankind had to argue that *MSN* will be (and should be) affirmed, but that this would be a surprising result (hence the exceptional circumstances). Plaintiffs had to argue that *MSN* will not be (and should not be) affirmed, but that this would be the expected result (hence, no exceptional circumstances). For that matter, if *MSN* is affirmed, maybe the opinion will say something about whether it flowed obviously from the existing law or not. Or maybe it will be a split decision. Or maybe the Supreme Court will grant certiorari in *Collect*. None of this matters. Just as here, the arguments addressed in *MSN* were made by skilled and experienced lawyers. Those arguments were doubtless made reasonably but in the face of uncertainty. And there are probably many other creative arguments that could be reasonably made and have not yet been decided by the Federal Circuit. That’s just how the law is sometimes — all the more true for patent law and quintessentially true for obviousness-type double patenting. The point is that Mankind must be understood to have taken all of this into account when it made the stipulation, so the result of *MSN* does not justify vacating it.

12. Furthermore, vacating the stipulation to allow Mankind to assert an invalidity defense would prejudice plaintiffs. We agree with Mankind that the prejudice is not extreme given the nature of the defense and the stage of the case, but it remains that plaintiffs and Mankind made a calculated deal to avoid the issue of invalidity, and plaintiffs have relied on that deal. Invalidity contentions were due nearly a year ago and the deadline for fact discovery has passed. Regardless of how easy Mankind believes it will be for plaintiffs to respond to Mankind's invalidity arguments, Mankind's promises entitle plaintiffs to repose.

13. Together, the relevant factors in *Waldorf* weigh against vacating. Holding the parties to the stipulation will not cause Mankind to suffer manifest injustice, and vacating the stipulation will be prejudicial to plaintiffs. Mankind's motion to vacate is therefore denied, along with its motion to amend the Answer.


MURPHY, J.